

## **REMARKS**

Claim 27, which was amended to recite that the assembled implant is “helically” threaded, is supported by Applicants’ FIGs. 3A-12D, showing helical threading. Claim 27, which was also amended to recite that the threaded sections have a “circular cross section,” is supported throughout the specification and particularly at FIGs. 3C, 4C, 6C, 7B, 7C, 7D, 8C, 9B, 10A, 10B, 11B and 12B. Accordingly, the amendments to claim 27 do not add new matter.

### **Summary of the Basis for Rejection**

Claims 11-14, 16-20, 22-23, 25, and 27-33 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Patent No. 6,200,347 (“Anderson”) in view of U.S. Patent No. 5,906,616 (“Pavlov”).

The Applicants will address this sole basis for rejection in Section I, respectively, which follows.

#### **I. 35 U.S.C. § 103(a) over Anderson in view of Pavlov**

##### **A. The Combination of Anderson and Pavlov Fail to Make a *prima facie* Case of Obviousness Against the Invention As Claimed**

Claims 11-14, 16-20, 22-23, 25, and 27-33 are solely rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Patent No. 6,200,347 (“Anderson”) in view of U.S. Patent No. 5,906,616 (“Pavlov”). Claims 11-14, 16-20, 22-23 and 25 have been cancelled by amendment herein. Accordingly, only claims 27-33 are subject to this basis for rejection.

Claim 27 is independent. Claims 28-33 ultimately depend from claim 27. Claim 27 is directed to “An assembled helically threaded implant” that comprises two or more helically threaded sections of “cortical bone.” In addition, the sections of cortical bone have “a circular cross section.” Claims 28-33 incorporate these elements by reference to claim 27.

According to the Patent Office, “[w]ith respect to claims 11, 20, 27, Anderson et al discloses an assembled implant, as best seen in the figures, for implantation between adjacent vertebrae in the spine of a patient comprising two or more sections of cortical bone; as best seen in FIGS. 1-10, that are **joined in tandem** by a pin (7, 9, 13) to form an implant that is longer than it is wide, as best seen in FIGS. 9, 10, the pins interconnecting the section to form an **elongated body** from about 5mm to about 25 mm in length, wherein **all longitudinal surfaces are continuously tapered and protruded, readable as threaded** (since Anderson et al. disclose in column 6, lines 50-52, column 7, lines 1-13, surfaces including continuous protrusions) the elongated body also having also having a first diameter for initially engaging adjacent vertebrae and an opposing end having a second diameter that is larger than the first diameter (since Anderson et al. disclose in column 6, lines 39-40 that the bone graft is a tapered cylinder); as set forth in column 8, lines as set forth in column 23, lines 1-67, column 31, lines 1-22 and as best seen in the figures.” [Official Action at page 2-3 (bridging sentence); emphasis added in bold.] The Applicants respectfully disagree.

As an initial matter, the Applicants disagree with the Patent Office’s characterization of FIGs. 1-10 of Anderson as showing sections of cortical bone “joined in tandem.” The word “tandem” is ordinarily understood to mean connected head to tail - **one behind the another:**

**tandem – one behind another, in single file**

[Exhibit C of Response to the Official Action of 10/04/04:  
Webster’s New World Dictionary, Second College Edition,  
Guralink, Ed., Prentice Hall Press, Cleveland OH, at page 1453;  
emphasis added in bold.]

In contrast, the word “abreast” means “side-by-side” when going forward:

**abreast – side by side, as in going or facing forward**

[Exhibit C of Response to the Official Action of 10/04/04:  
Webster’s New World Dictionary, Second College Edition,  
Guralink, Ed., Prentice Hall Press, Cleveland OH, at page 4;  
emphasis added in bold.]

Thus, the words “tandem” and “abreast” are direction terms relative to a particular use. By analogy, a tandem trailer truck has two semi trailers connected head to tail. [See Exhibit A: American Heritage Dictionary of the English Language, 4<sup>th</sup> Ed. 2000 “**tandem trailer** – a trucking rig consisting of a tractor pulling two trailers, one behind the other.”]. If the Examiner has evidence that the opposites “tandem” and “abreast” mean the same, then it is respectfully requested that he submit a declaration, affidavit or evidence from the Applicants’ specification supporting such an unconventional definition.

Consistent with the ordinary meaning of the word “abreast,” FIGs 1-8 of Anderson show sections of bone connected “abreast” and not in “tandem.” Specifically, Anderson describes FIGS. 1-6 therein as follows:

FIG. 1. FIG. 1 illustrates a perspective view of a trapezoid **wedge** composite bone graft having a non-textured surface.

FIG. 2. FIG. 2 illustrates a side view of a trapezoid **wedge** composite bone graft having opposing textured surfaces provided perpendicular to the interfaces of the bone portions. The textured surfaces illustrate continuous linear protrusions defining a saw-tooth-like pattern.

FIG. 3. FIG. 3 illustrates a **cross-section** posterior view of the trapezoid **wedge** composite bone graft of FIG. 2.

FIG. 4. FIG. 4 illustrates a **cross-section** anterior view of the trapezoid **wedge** composite bone graft of FIG. 2.

FIG. 5. FIG. 5 illustrates a top view of the trapezoid wedge composite bone graft of FIG. 2, and having a textured surface.

FIG. 6. FIG. 6 is a perspective view of the trapezoid wedge composite bone graft of FIG. 2, and having a textured surface

[Anderson at col. 8, lines 48-59; emphasis added in bold.]

FIG. 1 of Anderson is directed to a “wedge” comprised of three segments. Each of FIGs 2-6 of Anderson is directed to a different view of the same “wedge” of FIG. 2. The wedge of FIG. 2 differs solely from the wedge of FIG. 1 in that the latter has (upper and lower) opposing “toothed surfaces. The term “wedge,” as used by Anderson to describe the objects of FIGS. 1-6 defines the object’s shape, its function, as well as its

direction of use. In order to be a wedge, the wedge advances forward from the shorter leading height 11 of FIG 1 to the higher trailing height 13 of FIG. 1. As a result, the bone portions in FIGS 1-6 of Anderson are inherently and operatively connected side-by side (abreast) to the direction of advancement of the wedge. Consistent with this interpretation, Anderson refers to 12 of FIGs 1, 3 and 4 as being the “width” meaning that the sections are connected “abreast” and not in tandem.” [See Anderson at col. 20, lines 2-3 (“composite width 12”); line 12 (“composite width 12”); and line 15 (“composite width 12”).] One skilled in the art would have no reason to construe the teachings of Anderson other than what they say. The direction of advancement of the wedge is further corroborated by the direction of the parallel rows of teeth shown in FIG. 2. The parallel rows of teeth run parallel to the “width” 12 to engage the upper and lower surfaces of the vertebrae and resist sliding out which is a movement perpendicular to the rows of the teeth. Thus, FIGs. 1-6 of Anderson, which show bone segments connected “abreast,” fail to show segments of cortical bone connected in tandem as alleged by the Patent Office. Separately, the segments of bone used in FIGS. 1-6 of Anderson are shown in the “cross-section” views of FIGS 3 and 4 as having cross sections that are rectangular. Thus, none of the segments of cortical bone used in FIGS. 1-6 have a cross section that is “circular” as recited in claim 27. Moreover, the description of FIG. 2 of Anderson refers to the parallel rows of ridges shown in FIGS. 2, 5 and 6 as “continuous linear protrusion,” they are only continuous along respective opposing linear surfaces. They do not teach or suggest a helical thread as recited in claim 27. For all these reasons, the Patent Office erred in its’ finding that FIGS 1-6 of Anderson disclose bone segments connected “in tandem.”

The Patent Office also erred in finding that FIGs. 7-8 disclose cortical bone segments connected in tandem. FIG 7 of Anderson shows two segments of cortical bone “slideably connected” by bone pins. The direction of the rows of teeth on sections 16 and 17 of FIG. 7 show that the implant is inserted perpendicular to the rows of teeth so that the teeth can grip the vertebrae. Based upon the structure and orientation of the teeth, the sections of cortical bone 16 and 17 are “abreast” to one another and not in “tandem.” If the device were inserted in the direction of the pins and teeth, the

“slidable” connection would allow the connecting pins to protrude beyond the first bone segment as the first bone segment meets resistance while the second bone segment is moving forward. The protrusion of the bone pins beyond the leading bone segment would pose an unacceptable risk of impaling the spinal column on the patient, and thus, would not be inserted in that direction. FIG. 8 is merely “a top view of the slideably connected composite bone graft of FIG. 7 . . . having a cancellous bone portion disposed there between.” [Anderson at col. 9, lines 3-6.] For this reason, the Patent Office erred in finding that FIGS 7 and 8 of Anderson depict cortical bone segments connected in tandem.

FIGs 9 and 10 of Anderson are non-directional. FIG 9 depicts 3 rectangular segments of bone connected by two bone pins. According to Anderson “FIG. 10 illustrates a preferred cortical dowel composite bone graft including a plurality of cortical bone portions connected by a **single cortical bone pin** inserted into a through-hole.” [Anderson at col. 9, lines 9-12.] FIG. 10 is the only Figure in Anderson showing any assembled implant having a circular cross-section. However, FIG. 10 does not show an assembled implant “wherein **all longitudinal surfaces are continuously tapered and also threaded.**” In fact, the Patent Office has admitted on page 3 of the Office Action that “**Anderson did not teach of threads on the surface of the implant. . .**” Further, the assembled dowel of FIG. 10 is not tapered.

In addition to admitting that “**Anderson did not teach of threads on the surface of the implant,**” the Patent Office also admits “Anderson does not teach . . . a slot on the second end to drive the implant.” [Official Action at page 3; emphasis added in bold.] To make up for these deficiencies, the Patent Office cites to Pavlov. However, Pavlov is directed to an anterior fusion “cage” (Title), not an implant composed of bone. Moreover, the “cage” of Pavlov is made of a “**titanium metal or alloy such as Ti64.**” [Pavlov at col. 9, lines 54-55; emphasis added in bold.] Like any cage, the cage of Pavlov is a hollow shell a plurality of openings to the outside. According to Pavlov, “The fusion cage defines an **internal cavity and apertures** through the wall of the cage which communicate the external cylindrical surface with the internal cavity.” [Pavlov at col. 1, lines 25-29.] One skilled in the art would not look to machined titanium, and

particularly titanium cages, for inspiration on shapes for bone implants. Moreover, the cited art fails to teach or suggest that cortical bone, as claimed by the Applicants, is a suitable equivalent of titanium for a continuously tapered and threaded implant that needs to be screwed into position. It is **impermissible** to use hindsight to **pick and choose** only certain parts of Pavlov (*i.e.*, threads), while disregarding others (hollow cage, titanium) and combine it with assembled cortical bone to arrive at the Applicants' invention. *See Bausch & Lomb, Inc. v. Barnes-Hind Int'l, Inc.*, 230 USPQ 416, 420 (Fed. Cir. 1986), quoting *In re Wesslau*, 147 USPQ 391, 393 (CCPA 1965) ("It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art."). For all these reasons, the combination of Anderson and Pavlov fails to make a *prima facie* case of obviousness against claims 11-14, 16-20, 22-23, 25 and 27-33.

**B. Claims 27-33 include a Limitation ("pins conveying a tortional load") that is neither Taught nor Suggested in Anderson or Pavlov, Alone or in Combination**

Pavlov teaches the use of a single piece titanium cage that optionally has a cap. Pavlov neither teaches nor suggests an assembled cage nor the use of pins as components of its cage for any purpose. Thus, the only reference teaching or suggesting the use of any pins is Anderson.

Claim 27 has been amended from "pins suited for conveying a tortional load . . ." to "pins ~~suited for~~ conveying a tortional load between said threaded sections as said threaded sections are rotatedly advanced between said vertebrae." Relying upon the prior language, the Patent Office contends that "the pins of Anderson et al are **suited for** conveying tortional load, see pin (7) of FIGS. 35, 37, 43, 44, and as set forth in column 14, lines 40-45, lines 55-58. The Applicants respectfully disagree.

FIG 35 of Anderson is a "standing" [col. 10, line39] view, showing the top "textured surface 117a" [col. 24, line 10] of the stacked implant. The pin 7 in FIG

35 is standing vertically between the flat upper and flat lower surfaces of the implant and would not be inserted by rotational advancement during implantation or after implantation of this stacked implant. Rather, it would be slid in as a single unit (like a pancake) along its flat surface without twisting one layer of the stack relative to the other layer to achieve insertion. Cited FIGS 37, 43 and 44 show the same style stacked implant as FIG 35. None of these D-shaped stacked implants would be inserted by rotational advancement.

The only graft of Anderson that has a “circular” cross section is the graft of FIG 10. However, Anderson teaches that this graft has a “single cortical bone inserted” in a central through hole. The single centrally located bone pin would allow the circular bone segments to spin independent of one another and would not be able to convey torsional force between the bone sections to allow the implant to be rotatedly inserted as a single unit (if threaded). However, as admitted by the Patent Office, “**Anderson did not teach of threads on the surface of the implant. . .**” Thus, Anderson never even recognized the problem solved by the Applicants invention. Rather, Anderson discloses that “the one or more pins and the one or more through holes are configured to provide an interference fit for holding together the graft unit.” [Anderson at col. 5, lines 25-28.] Thus, based upon the flat structure of the stacked implants shown in Anderson, the purpose of the pins in Anderson is merely as stated, “holding together the graft unit.”

As a matter of law, the invention as a whole “mandates” consideration of the “problem solved.” *See In re Wright*, 6 USPQ2d 1959, 1962 (Fed. Cir. 1988) (“the requisite view of the whole invention mandates consideration of not only its structure but also its properties and the problem solved.”) However, in the present case, Anderson failed to even perceive the problem and thus, could not suggest a solution. Pavlov’s used a machined hollow cage that was machined from a single piece of titanium. Thus, the combination of Anderson and Pavlov fails to address the problem of conveying torque along the length of a tandemly “assembled” continuously tapered and threaded circular implant of the Applicants’ invention. For all these reasons, the combination of Anderson over Pavlov would not have rendered obvious the invention as

a whole of claims 27-33 of Applicants' invention. The allowance of claims 27-33 is respectfully requested.

## SUMMARY

Claims 11-14, 16-20, 22-23, 25, and 27-33-26 stand rejected. Claims 11-14, 16-20, 22-23 and 25 have been cancelled. Accordingly, claims 27-33 are pending.

In view of the amendments and arguments provided herein, all bases for rejection of claims 27-33 under 35 U.S.C. § 103(a) for allegedly being obvious over Anderson in view of Pavlov have been rebutted.

For all these reasons, claims 27-33 are in condition for allowance.

Respectfully submitted,

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Date: July 19, 2006

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The American Heritage® Dictionary of the English Language: Fourth Edition. 2000.

## tandem trailer

NOUN: A trucking rig consisting of a tractor pulling two trailers, one behind the other.

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